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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/699,679	10/30/2000	Evan C. Unger	UNGR-1598	8248

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/699,679

Applicant(s)

UNGER ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 and 54-60 is/are pending in the application.
- 4a) Of the above claim(s) 5, 12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-11, 14-35 and 54-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 24. 6) ☐ Other: _____

DETAILED ACTION

Amendment filed on October 02, 2003 has been entered. Claims 1-35, 54-60 are pending. Applicant has election of Group IIXII in Paper No. 22B. Applicant's election of species has further been acknowledged accordingly the search is directed to such species wherein R1 is acyl of 18 carbons, R2 is H, R3 is ethylene, R4 is acyl of 18 carbons, P is PEG-3400 and T is a peptide having sequence CRGDC wherein the two cytosines are linked together via a disulfide linkage. Claims 1-4, 6-11, 14-35 and 54-60 are directed to said species and thus under consideration.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly, claims 1-35, 54-60 are examined to the extent that they are read on Group XII invention. Other inventions enumerated as Groups I-XI are thus withdrawn as being directed to the non-elected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Claims 5, 12-13 are also withdrawn from further consideration because they are not directed to the elected species.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6-11, 14-35 and 54-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger et al WO 96/40285 ("WO '285") in view of Ruosiahti et al US Patent 5,536,814 and Siegel et al US Patent 6,086,573.

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Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive. Applicant argues that the WO '285 does not teach di-fatty acid amide compounds. Applicant also states that the vast majority of the compounds of W) '285 include a tertiary carbon atoms that are substituted with chemical groups other than amide groups. (see Amendment at pages 12-13).

This argument is not persuasive because contrary to applicant's contention WO '285 teaches difatty acid amide compounds. See for example the core carbon atom of the compound of page 179, lines 13-15. This carbon atom is linked to R2-X1-R1 at one end, X1-R1 at the other, and R3 at the other position. R2 is defined as an alkylene moiety of 1-30 carbons encompassing an ethylene. X1 can be -NR4 wherein R4 is a hydrogen or alkyl. Such moiety meets the limitation of instant N-R5. Finally, R1 of the prior art is an alkyl of 1-50 carbons, which reads on the instant R4, and R2 as an acyl group. All other limitations are described below as the corresponding groups. (see claim 136-149, page 179-182; claim 164, page 183). The corresponding functional groups in the compounds of WO '285 are as follows:

Functional Group of the Instant Compound	Instantly Elected Species	Functional Group of the Compounds of WO '285	Corresponding Subgenus	Citation
X1, X2	C=X3, C=X3-N(R8), -C=X3-N(R8)-C(=X3)-, wherein X3 is O or S	X2, X3	R5-X4-C(=X5)-, R5-C(=X5)-X4, -X4-C(=X5)-R5, R5-X4-C(=X5)-R5-C(=X5)-X4, wherein X1 is NR4, R3 is a H, R4 is an alkyl 1-10 carbons, R5 is a direct bond, X4 is O, NR4 or S, and X5 is O or S	Page 179, lines 15-22, 25-27. Page 180, lines 1-5
N-R3-CH and N-CH	N-R3-CH, N-CH	-R1X1-R2C-R3, and -R1X1-C-R3	R3 = H, X1 = -NR4, R4 = H, R1=Alkyl, R2=Alkylene	Page 179, lines 13-28.
R3	Alkylene	R2	Alkylene of 1 to 30 carbons	Page 180, line 1
R1, R2	Acyl of 18 carbons	R1	Alkyl of 1-50	Page 179, line

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			carbons	27
P	Peg-3400	Z	Hydrophilic polymer, such as PEG, preferably having MW of about 2000-5000	Page 179, line 25. page 44, lines 1-6
T	CRGDC peptide	Q	Cyclic peptides	Page 179, line 26. page 183, line 13-15. pages 50, 55-58

Therefore, contrary to applicants' arguments such configuration of molecules would have led to a di-fatty acid amide as described above.

Ruoslahti and Siegel further complement the teachings of WO '285 by providing specific information about the instant CRGDC and thrombolytic agents. Ruoslahti is used to show that CRGDC is a cyclic peptide and a suitable targeting agent for recognizing fibronectin- and vitronectin-binding integrins of cell surface. Specifically, Ruoslahti teaches that CRGDC motif include the following amino acid sequences of cys-arg-gly-asp-cys (see abstract, col 2, lines 35-41; Seq ID 10, col 15) which is the same as the instant targeting agent CRGDC.

Siegel is used to merely show that combination of a thrombolytic agent such as urokinase with a gaseous ultrasound contrast agent enhance thrombolytic effects of the thrombolytic agent. (see abstract, col 6, line 65-col 8, line 20).

Accordingly all elements of the instant compounds are taught by the prior art references. Therefore, the rejection is proper because of the reasons of record.

Conclusion


No claims are allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.


RUSSELL TRAVERS
PRIMARY EXAMINER